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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,742	12/17/2003	Johann Leban	242261US0	5613
59554 7590 03/07/2007 Womble Carlyle Sandridge & Rice, PLLC Attn: Patent Docketing 32nd Floor P.O. Box 7037 Atlanta, GA 30357-0037			EXAMINER COPPINS, JANET L	
			ART UNIT 1626	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/07/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/736,742

Applicant(s)

LEBAN ET AL.

Examiner

Janet L. Coppins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-8 are pending in the instant application.

Information Disclosure Statement

1. Applicants' Information Disclosure Statements (IDS), submitted June 2, 2004 and July 12, 2004, have been considered by the Examiner. Please refer to the attached copies of Applicant's PTO-1449 forms submitted herewith.

Election/Restrictions

2. Applicant's election **with traverse** of the invention of Group I, compounds of claims 1-4, and the specific compound of in the reply filed on January 26, 2007 is acknowledged. Accordingly, claims 5-8 are currently withdrawn from consideration as drawn to non-elected subject matter. The traversal is on the ground(s) that products and their methods of manufacture and use should be examined together in the same application, per the guidelines of *In re Ochiai*.

3. This is not found persuasive because in accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other members obvious under 35 U.S.C. 103. The expression "special technical features" shall mean those technical features that define a contribution which each of the

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claimed inventions, considered as a whole, makes over the prior art. The 'special technical feature' must a) occupy a large portion of the core structure, or b) the 'special technical feature' constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation from knowledge in the art that all members will behave in the same way. Thus, the technical relationship and the corresponding special technical feature result from a common (or equivalent) structure that is responsible for the common activity (or property). Applicants' instant claims do not contain a 'special technical feature', since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain a disubstituted heteroaryl backbone (containing an amine group) in common, which does not define a contribution over the prior art (**variables excluded**). Attached to the instant office action is a copy of a reference that provides that the technical feature, which can be taken as a whole amongst all the alternatives, as depicted above, is not a 'special technical feature', by failing to define a contribution over the prior art, as it was known in the art prior to the filing of the instant application. Please refer to U.S. patents 5,258,357 and 6,747,041 B1, referenced below, which disclose the same "special technical feature," and support the Examiner's position that Applicants' compounds fail to define a contribution over the prior art. Therefore, since the substituents on the technical feature vary extensively (for example "Y" can be hydrogen, halogen, alkyl, cycloalkyl, heteroaryl, etc) and when taken as a whole result in vastly different compounds and unity of inventions is

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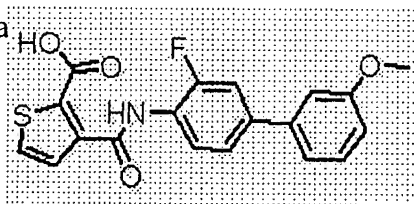
considered to be lacking and restriction of the invention is considered to be proper. The requirement is therefore made FINAL.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Status of the Claims

5. Claims 1-8 are pending in the instant application. Claims 26-45, as previously stated, are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

The scope of the invention of the elected subject matter is as follows (please refer to page 10 of the application for the elected subject matter):



Compounds of formula (II), as depicted in claim 1, wherein: "A" is thiophene or furan (i.e. X is S or O); Z¹ and Z² are O or S; R² is H, OR⁶, NHR⁷, NR⁷, OR⁷, or R² (excluding any heterocycles); and the remaining variable are as defined in the claims.

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As a result of the election and the corresponding scope of the invention identified above, the remaining subject matter of claims 1-4 are withdrawn from further consideration pursuant to 37 CFR 1.142(b). Accordingly, remaining claims 2-4 contain subject matter that is withdrawn in part. The withdrawn compounds contain varying functional groups such as imidazolyl, thiazolyl, oxazolyl, isoxazolyl, triazolyl, pyrimidinyl, pyrazinyl, etc which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. and international classification systems. Therefore the subject matter which are withdrawn from consideration as being non-elected subject matter differ materially in structure and composition and have been restricted properly and a reference that anticipates the elected compound(s) would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 4 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 provides for a compound of claim 1 as well as its "use as a medicament," but, since the claim does not set forth any steps involved in the method/process, it is unclear whether Applicants are attempting to claim a compound or a method, and if a method is intended, what method/process applicant is intending to

encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

8. 35 U.S.C. 101 reads as follows:

9. Claim 4 is also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-4 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 5,258,357 to Muenster et al (herein referred to as "the '357 patent). The '357 patent discloses thiophene-carboxamides and furan-carboxamides that are the same as those instantly claimed, please refer to compounds of formulae Ia, Ib, or Ic in columns 1-4 wherein "x" is O or S, and "R¹" or "R²" contain at least one aromatic ring; please see RN 135278-59-0, RN 135278-55-6, RN 135278-54-5, and RN 135278-21-6, for example.

12. Claims 1-4 rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6,747,041 B1, Katsuhira et al (herein referred to as "the '041 patent"), with a 371 (c)(1),(2),(4) date of April 10, 2002. The '041 patent discloses heterocyclic dicarboxamide compounds of Formula (I) that are the same as those instantly claimed, please refer to columns 1-9. The '041 patent specifically teaches compounds wherein "Het" (corresponding to Applicants' "A" ring) is thiophene or furan, please refer to Tables 21-24, columns 67-72, compounds wherein "W" is O or S; "Het" is Q¹¹, Q¹², or Q¹³; Z¹ and Z² are O; and R¹ is alkyl. Please refer to RN 314762-88-4, RN 314762-89-5, RN 314762-90-8, RN 314762-91-9, RN 314762-92-0, RN 314762-93-1, RN 314763-03-6, RN 314763-04-7, RN 314763-05-8, RN 314763-06-9, and RN 314763-07-0.

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Conclusion

13. In conclusion, claims 1-8 are pending, claims 5-8 are withdrawn from consideration, and claims 1-4 stand rejected.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Coppins
March 4, 2007


Joseph K. McKane
SPE, Art Unit 1626